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# Aerotel Medical Systems (1998) Ltd. 510(k) Submission BP-Tel Trans-Telephonic Blood Pressure Measurement System

## 510(k) Summary

### (1) Submitter Information

Name: Aerotel Medical Systems (1998) Ltd.

Address:

5 Hazoref Street 58858 Holon Israel

Telephone Number: 972-3-559-6111

Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: June 3, 2004

### (2) Name of Device

Trade Name: MPM System

Common Name: Device for transmitting measurement parameters from the home and receiving them at

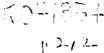
a central station with Internet Access.

Classification name: Telephone electrocardiograph transmitter and receiver.

### (3) Equivalent legally-marketed devices.

- 1. Cybernet Medical Medstar, K020534
- 2. Aerotel BPTEL/MPM, K983717
- 3. Aerotel TeleCliniQ, K021447
- 4. Aerotel MPMP-Net, K030825

### (4) Description



The system comprises a modem-like device that connects to various cleared measurement devices and a strain station program that keeps the records of the patients, prepares reports, and makes the reports available that the internet.

### (5) Intended Use

The Aerotel MPM SYSTEM is intended to be used with home patient monitoring devices (blood pressure, digital scale, blood glucose level, respiratory peak flow, pulse oximetry) to send the measured data to a central station via modem by telephone, where reports can be generated for the physician and reports can be received over the Internet by physicians and patients.

## (6) Performance Data

#### (a) Non-clinical tests

The system has been tested with all of the compatible measuring units and has satisfactorily passed the tests. The software has been extensively validated.

### (b) Clinical tests

Clinical tests are not necessary because the device does not use new technology/

### (c) Conclusions

The MPM system is equivalent in safety and efficacy to the legally-marketed predicate devices.



OCT 6 - 2004

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Aerotel Medical Systems, Ltd. c/o George H. Myers, Sc.D. Medsys, Inc. 377 Route 17 S Hasbrouck Heights, NJ 07604

Re: K041854

Trade Name: MPM System

Regulation Number: 21 CFR 870.1130

Regulation Name: Noninvasive Blood Pressure Measurement System

Regulatory Class: II (two)
Product Code: DXN
Dated: July 7, 2004

Received: July 8, 2004

### Dear Dr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

# Page 2 - George H. Myers, Sc.D.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <a href="http://www.fda.gov/cdrh/dsma/dsmamain.html">http://www.fda.gov/cdrh/dsma/dsmamain.html</a>

Sincerely yours,

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

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|---|--|
| 510(k) Number (if known): <u>K041854</u>  |  |
| Indications for Use Form  |  |
| Device Name: MPM System   |  |
| Indications for Use:  |  |
| The Aerotel MPM SYSTEM is indicated when patients monitoring devices (blood pressure, digital scale, blood peak flow, pulse oximetry) and wish to send the measu via modem by telephone, where reports can be generate can be received over the Internet by physicians and pati | glucose level, respiratory red data to a central station d for the physician and reports |
| (PLEASE DO NOT WRITE BELOW THIS LINE – C<br>PAGE IF NEEDED)   | ONTINUE ON ANOTHER   |
| Concurrence of CDRH, Office of Device Ex  | valuation (ODE)  |
|   |  |
| Prescription UseOR  | Over-the-Counter   |
| Use(Per 21 CFR 810.109)   | (Optional Format 1-2-96)   |
| Division Sign-Off) Division of Cardiovascular Devices 510(k) Number_K04/85  | _  |
|   | <del>-</del>   |